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<b>(21) International Application Number:</b> PCT/BG99/00025 <b>(22) International Filing Date:</b> 11 November 1999 (11.11.99)  <b>(30) Priority Data:</b> 102912 11 November 1998 (11.11.98) BG  <b>(71)(72) Applicant and Inventor:</b> IGNATOV, Nikola Gueorguiev [BG/BG]; Victor Grigorovich Street, 12, 1606 Sofia (BG).		<b>(81) Designated States:</b> JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.          Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
<b>(54) Title:</b> INTRAMEDULLARY DEVICE FOR FIXATION, COMPRESSION AND TRACTION  <b>(57) Abstract</b> <p>The device consists of two metal tubes (4) and (5) one inside the other. The inner tube or slider (5) has in its top end threads with a feed screw (1) situated therein. The screw (1) passes through a bearing (2) welded to the outer tube (4), and under and above the bearing there is a stopper (3). There are holes drilled in the opposite walls of the outer tube (4) immediately under the bottom end of the screw (1). Under the holes, bilaterally on the outer tube (4), there are longitudinal slots. On the slider (5) there are holes of the same size as those on the outer tube (4), and above them, longitudinal slots cut bilaterally and having a size corresponding to that of the slots on the outer tube (4). The holes on the outer tube are disposed opposite the slots on the slider, while the holes on the slider are disposed opposite the slots on the outer tube. The device can serve for fixation, compression and traction rather than only passive fixation.</p> <div data-bbox="1063 1165 1380 1953"> </div>		

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## **INTRAMEDULLARY DEVICE FOR FIXATION, COMPRESSION AND TRACTION**

### **Field of the Invention**

The invention relates to an intramedullary device for fixation, compression and traction of the femur in the treatment of various kinds of fractures, and is used in the field of orthopaedics and traumatology.

### **Prior Art**

It is known that for the treatment of various kinds of fractures of the femur, in addition to metal plates and screws for fixation of the bone fragments, there are used also different Kuntscher and other nails for intramedullary fixation.

One of the most frequent complications that occur when using plates and screws is the bending or breaking thereof, resulting in deformation or non-union of the bone. The fixation here is static. One of the weak points of the medullary nails is that they cannot always ensure stability of the fragments, and there is always a risk of their dislocation. For the purpose of increasing the stability of the fracture site, surgeons started to ream the medullary canal in order to insert tight fitting nails. However, later investigations showed that reaming of the medullary canal leads to severe damage of its blood supply.

In order to avoid this negative moment of the intramedullary osteosynthesis, the so-called interlocking nails have recently been invented and applied, said nails having holes in their top and bottom ends. Screws are inserted through the proximal and the distal fragments and respectively through the holes of the medullary nails. Thus the fragments get blocked and the above-mentioned dislocations are avoided. This is what the inventors call static fixation. If no transverse screw is inserted through one of the fragments, it gets free and axially pressed to the fixed fragment, this being

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called dynamic fixation. According to this method, the static fixation cannot ensure an adequately close and continuous contact between the fragments, and in the so-called dynamic fixation one of the fragments is unstable. The interlocking intramedullary nails are most suitable for comminuted fractures of the long bones needing static fixation.

Along with the above-mentioned osteosynthetic devices, the so-called external fixators are also used in practice. In this case, a great number of Kirschner wires or pins are inserted through the skin into the fragments, the outer ends of said pins being affixed to a system of metal planes, rods and screws placed outside the human body. This system moves the wires or pins, and the fragments together with them, to one or another direction. The external fixators are used for the treatment of some kinds of fresh fractures, delayed union and non-union of fractures, lengthening or shortening of limbs, and some other orthopaedic cases. They are useful also in the treatment of infected fractures.

The most essential disadvantages of the external fixators are:

- development of pin tract infections;
- it may be difficult for surgeons who are not well acquainted with the fixators to assemble them;
- the fixators often are coarse, cumbersome and uncomfortable for the usual clothes of the patients;
- there is a risk of refractures after removing the fixator, therefore there is a necessity of an additional external protection of the leg until the full consolidation of the bone, which may take a lot of time;
- imprudent and improvident patients may damage the apparatus;
- restraint of the muscles from their normal excursion, muscle fibrosis and a risk of tendon rupture.

In some types of fixators:

- it is inconvenient to perform additional open procedures in the region of the pathological site; besides there is an additional risk in case of infection along the pins tract;

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- impossibility, or limited possibility for correction of dislocations of the fragments. Besides, additional skills and efforts are required for that purpose.

### **Technical Substance**

The device consists of two metal tubes with different diameters, situated coaxially one inside the other and having a profile similar to that of a Kuntscher nail. In the top inside end of the inner metal tube or slider there are threads with a screw situated therein, whose length may vary depending on the case. The top end of the screw passes through a bearing welded to the outer tube, a stopper being situated under and above the bearing. Immediately under the bottom end of the screw, on the two opposite walls of the outer tube, there are drilled transverse holes at an equal distance (1-2 cm) from each other. Under the distal hole there is a longitudinal slot on each of the two sides of the outer tube, the length of which can vary. The slider also has holes of the same size as those on the outer tube, but in its distal part. Above the holes, there are longitudinal slots cut bilaterally on the slider and having a size corresponding to the slots on the outer tube. Thus the holes on the outer tube are disposed exactly opposite the slots on the slider, and the holes on the slider are disposed the same way opposite the slots on the outer tube. The top end of the outer tube is cylindrical and has outside threads at a length of approximately 1 cm.

### **Description of the Figures Enclosed**

Fig. 1. represents a scheme of the principles of operation of an intramedullary device for fixation, compression and traction of the femur.

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### **Embodiments**

According to an embodiment of the invention, an intramedullary device for fixation, compression and traction of the femur consists of two metal tubes (4, 5) with different diameters, coaxially disposed one inside the other. Both tubes have a profile similar to that of a Kuntscher nail. The inner tube or slider (5) has in its top end threads with a feeding screw (1) disposed therein. The top end of the screw (1) passes through a bearing (2) welded to the outer tube, and under and above the bearing there is disposed a stopper (3). Immediately under the bottom end of the screw (1) there are transverse holes drilled on the opposite sides of the outer tube (4) at an equal distance (1-2 cm) from each other. Under the distal hole there is a longitudinal bilateral slot cut on the outer tube (4), whose length may vary. The slider (5) also has holes of the same size as those on the outer tube, but in its distal part. Above them, there are bilateral longitudinal slots on the slider having a size corresponding to the slots on the outer tube. Thus the holes on the outer tube are disposed exactly opposite the slots on the slider, while the holes on the slider are disposed the same way opposite the slots on the outer tube. The top end of the outer tube is cylindrical and has outside threads at a length of 1 cm.

### **Application of the Invention**

The construction of the present device allows a telescoping movement of the inner tube towards the outer one. When the device is applied in the region of the femur, the system comprising the two tubes and the feeding screw is introduced into the medullar canal of the two fragments by means of a tubular driver, which is screwed on the top end of the outer tube. After that, by means of a target device, through the proximal and the distal fragments there are inserted one or two (depending on the case) transverse screws having a diameter of 5 mm (6) and passing through the two opposite walls of the bone (7) and through the respective holes and slots on the metal

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tubes as well. So installed, the system can serve as a static fixator like the interlocking nails. When it is necessary to create forces of compression or traction of the fragments, the surgeon turns the longitudinal screw to one or another direction by means of a screw driver placed through the tubular driver. Due to the constantly acting forces of compression or traction in the system, the latter is rather stable, so that the surgeon does not have to try to insert it tightly into the femur canal in every case. The proper length of the device applied is to be complied with the fracture site level.

In cases where the device is used to lengthen a thigh, the top end of the tubular driver is left to stick a little bit out of the skin. It is covered by a sterile dressing and is opened only when accomplishing the daily lengthening, which is usually from 1 to 1,5 mm. The driver is unscrewed and removed after the lengthening has been accomplished, and the wound is sutured.

In all other cases the tubular driver is removed right upon the compression is over, and the upper end of the device is covered by the soft tissues.

The intramedullary device for fixation, compression and traction of the femur possesses the possibilities both of the interlocking nails for static fixation and those of the external fixators for dynamic compression and traction, avoiding at the same time the above-mentioned disadvantages of those methods. That is why it takes priority over the interlocking nails or external fixators in all cases, except for cases of infected fractures or infected non-union fractures.

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**LITERATURE**

1. CAMBELL'S OPERATIVE ORTHOPAEDICS Ninth Edition 1998
2. Grosse.A. : Manual for osteosynthesis for femoral and tibial shaft fractures., Kiel, West Germany, 1981, Howmedica international, inc.
3. Russel.T.A. and Taylor.J.C. : Russel - Taylor interlocking medullary nail system. Richards Medical Co, Memphis, 1984
4. Zickel.R.E. : A new fixation for subtrochanteric fractures of the femur; a preliminary report. Clin. Orthop. 54:115, 1967
5. Zickel.R.E. : An intramedullary fixation device for proximal part of the femur: nine years experience. J. Bone Joint. Surg. 58-A.866, 1976



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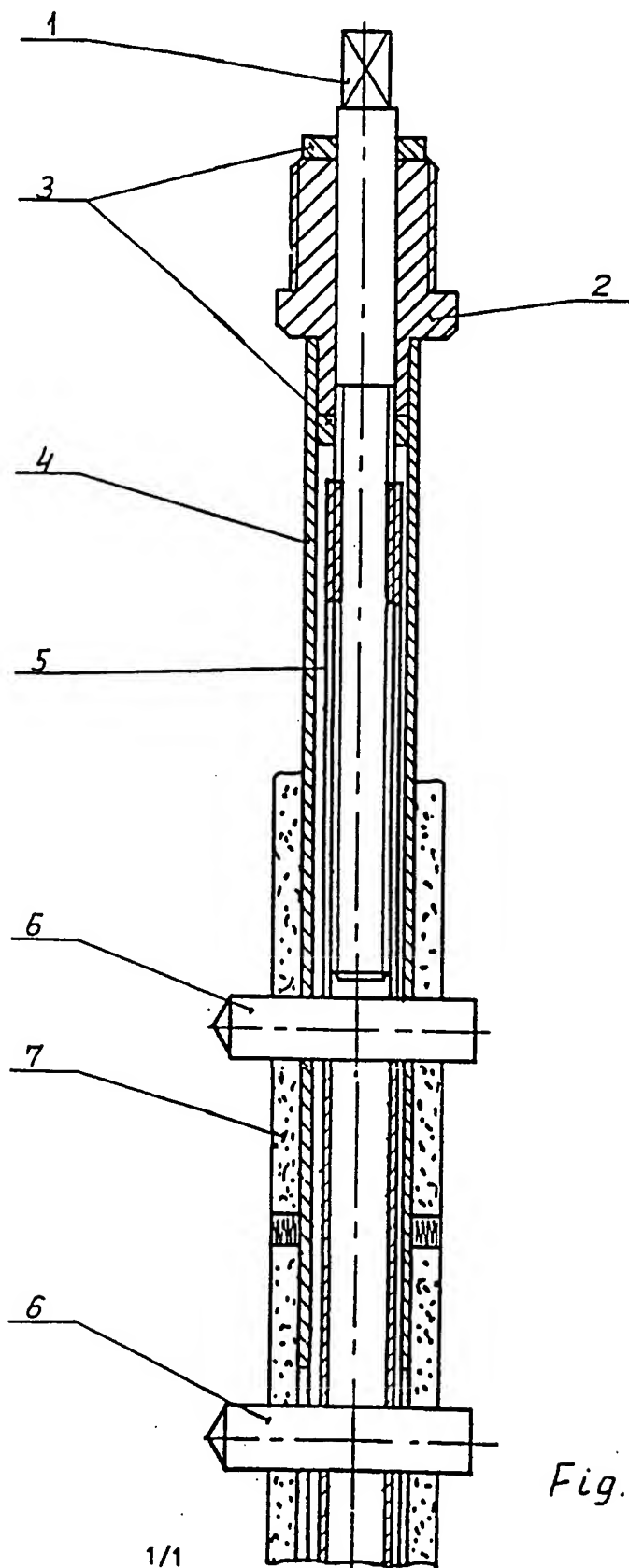
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**PATENT CLAIM**

An intramedullary device for fixation, compression and traction of the femur, *characterized by* that it consists of two metal tubes (4) and (5) with different diameters and the profile of a Kuntscher nail, the inner metal tube or slider (5) having in its top inside end threads with a feeding screw (1) disposed therein, the top end of the feeding screw passing through a bearing (2) with a stopper (3) under and above it, while under the bottom end of the screw (1) on the opposite sides of the outer metal tube (4) there are drilled holes at an equal distance one from the other, such holes being drilled in the distal part of the slider (5) as well, while under the distal hole of the outer tube (4) and above the proximal hole of the slider (5) there is cut a bilateral longitudinal slot.

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## INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61B17/72

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 85 33 134 U (INSTITUT STRAUMANN) 3 April 1986 (1986-04-03) page 13, line 16 -page 15, line 15; figure 5	1
A	WO 96 35387 A (UNIVERSITY OF WESTERN AUSTRALIA) 14 November 1996 (1996-11-14) page 4, line 15 -page 5, line 19; figure 1	1

☐ Further documents are listed in the continuation of box C.

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			DE      3541597 A	05-06-1986
			FR      2573978 A	06-06-1986
			GB      2167963 A,B	11-06-1986
			US      4875475 A	24-10-1989
WO 9635387      A		14-11-1996	AU      5492996 A	29-11-1996